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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,545	01/14/2002	Mahin D. Maines	176/60981 (6-11402-1001)	1814

7590

07/16/2003

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EXAMINER

SWOPE, SHERIDAN

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 07/16/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/045,545

Applicant(s)

MAINES, MAHIN D.

Examiner

Sheridan L. Swope

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 3, and 8-12 is/are pending in the application.
- 4a) Of the above claim(s) 3 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 8-12 is/are rejected.
- 7) ☐ Claim(s) 1 and 8-12 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Applicant's response, on March 8, 2003, Paper No. 10, to the first Office Action on the Merits of this case is acknowledged. It is acknowledged that applicants have amended Claims 1, 3, 8, and 9, and cancelled Claims 2, 4-7 and 13-26. Claim 3 is withdrawn as being drawn to a non-elected invention. Claims 1 and 8-12 and the species actin microspike formation of Claim 2 and epithelial cells in Claim 11 are hereby reconsidered.

#### *Claim Rejections - 35 USC § 112-First Paragraph*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Rejection of Claims 1 and 8-12 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained. The reasons for this rejection are presented in Paper No. 8. Applicants argue that the specification identifies two human BVR variants (SEQ ID NO: 1 and 3) and that the similarity between the two proteins, along with the polynucleotide of SEQ ID NO: 2, would allow one of ordinary skill in the art to prepare desired point mutations to arrive at SEQ ID NO: 3. In addition, the applicants state that the specification identifies rat BVR of SEQ ID NO: 4, encoded by SEQ ID NO: 5 and that other mammalian BVR nucleic acids can be identified using hybridization assays. Applicant's response also states that the structural features of BVR are described on page 9 and that fragments of BVR that contain one or more known functional domains can be prepared.

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These arguments are not found to be persuasive. Claims 1, 2, and 8-12 recite a method of modifying cell structure (with the elected species being actin spike formation) comprising increasing the intracellular concentration of any BVR or a fragment or variant thereof. Example 1 of the specification states that transfection of HeLa cells with biliverdin reductase-encoding DNA results in formation of actin spikes. However, the specification fails to describe the identity of the DNA used in Example 1. Furthermore, the specification fails to disclose which fragments or variants of BVR can be used in the methods of Claims 1 and does not describe which domains of BVR are necessary for actin spike formation. While methods to produce variants of a known sequence such as site-specific mutagenesis, random mutagenesis, etc. are well known to the skilled artisan, producing variants as claimed by applicants (i.e., regulating actin spike formation) requires that one of ordinary skill in the art know or be provided with guidance for the selection of which of the infinite number of variants have the claimed property. Without such guidance one of ordinary skill would be reduced to the necessity of producing and testing all of the virtually infinite possibilities. This would clearly constitute **undue** experimentation. While enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. Such guidance has **not** been provided in the instant specification. The specification does not establish: (A) regions of the protein structure which may be modified without effecting actin spike formation; (B) the general tolerance of any BVR to modification and extent of such tolerance in mediating actin spike formation; (C) a rational and predictable scheme for modifying any BVR residues with an expectation of obtaining the desired biological function; and (D) the

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specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful. Thus, rejection of Claims 1, 2 and 8-10 under 35 U.S.C. 112, first paragraph is maintained.

Rejection of Claims 1, 2, and 8-12 under 35 U.S.C. 112, first paragraph, for containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained. Applicants argue that the specification identifies a number of BVR variants and shows successful modification of HeLa cell structures. This is not found to be persuasive. The specification teaches modification of actin spike formation by only one BVR; and, the specific BVR used is not identified (Example 1). The specification fails to teach any other BVRs that can modify actin spike formation and the region of BVR that mediates actin spike formation has not been identified. Thus, one of ordinary skill in the art would not expect that methods using the unidentified BVR of Example 1 to modify actin spike formation is representative of the genus of methods claimed. Therefore, the genus of methods using BVR proteins and fragments and variants thereof that can mediate actin spike formation are not sufficiently described so that a skilled artisan would recognize that applicants were in possession of the claimed invention.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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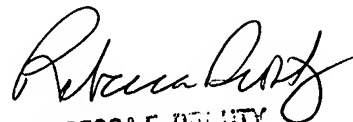
the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 703-305-1696. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sheridan Lee Swope, Ph.D.

  
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